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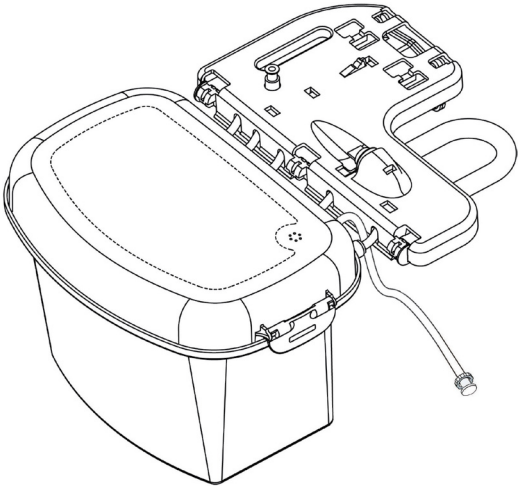
Organ Recovery
systems

LifePort® Kidney Transporter Disposable Oxygenation Perfusion Circuit



Instructions for Use

LifePort Kidney Transporter Disposable Oxygenation Perfusion Circuit is for use only with LifePort Kidney Transporter system.

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LKT201X

INDICATIONS FOR USE
LifePort Kidney Transporter (LKT) system is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient.

DEVICE DESCRIPTION
LifePort Kidney Transporter Disposable Oxygenation Perfusion Circuit is used to contain the kidney and perfusate under aseptic conditions during transport, with the option to introduce oxygen into the perfusate.

If oxygen is not being used, the Luer Lock Cap must be connected to the Oxygen Delivery Tube on the Oxygenation Perfusion Circuit or directly to the Perfusion Circuit to maintain aseptic conditions.

The complete LifePort Kidney Transporter system is comprised of the following components:

- LifePort Kidney Transporter (LKT100P/LKT101P/LKT101PNG)
- LifePort Kidney Transporter Disposable Oxygenation Perfusion Circuit (LKT201X)
  - Oxygenation Delivery Tube (900-00044)
  - Luer Lock Cap (900-00045)
- LifePort Kidney Transporter Disposable Sterile Drape (LKT300)
- LifePort Kidney Transporter Disposable Cannula (CAN/UCAN)

INSTRUCTIONS FOR USE
Prepare LifePort Kidney Transporter as described in LifePort Kidney Transporter Operator's Manual. Prepare KPS-1®, Kidney Perfusion Solution in accordance to the Instructions for Use. Maintain perfusate at proper temperature, approximately 2–8°C.

WARNING: Where noted, perform the following procedure on an aseptic field using aseptic technique.

1. *Using standard aseptic technique*, prepare a sterile field on a work table and introduce all necessary materials.
2. *Using standard aseptic technique*, remove LifePort Kidney Transporter Disposable Perfusion Circuit, Oxygenation Delivery Tube, and Luer Lock Cap from their respective packaging.

WARNING: Visually check LifePort Kidney Transporter Disposable Products before use. Do not use if parts are cracked, broken, or disconnected.

3. *Using standard aseptic technique*, remove Outer Perfusion Circuit Lid and Inner Perfusion Circuit Lid and place onto the sterile field.
4. *Using standard aseptic technique*, remove the Kidney Cradle and set aside within the sterile field.

CAUTION: Verify the Uptake Line is within the Low Fluid Detection Chamber inside the Organ Chamber.

5. *Perform this step using aseptic technique.* If oxygen is used, attach the Luer Lock Cap to the Oxygenation Delivery Tube and Oxygenation Delivery Tube to Oxygenation Perfusion Circuit. If oxygen is not used, attach the Luer Lock Cap directly to the Oxygenation Perfusion Circuit.

WARNING: The Luer Lock Cap must be applied to the Oxygen Delivery Tube or Oxygenation Perfusion Circuit to prevent leakage or contamination of the aseptic field.

6. *Using standard aseptic technique*, fill Oxygenation Perfusion Circuit with 1 Liter chilled (2–8°C) perfusate.
7. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid followed by the Outer Perfusion Circuit Lid.

WARNING: Oxygenation Perfusion Circuit inner surfaces are considered sterile, while outer surfaces are not considered sterile.

8. Place Oxygenation Perfusion Circuit into LifePort Kidney Transporter.
9. Position the Tubeframe upright, perpendicular to the Pump Deck. Insert the hinges into the receivers before rotating flat onto the Pump Deck.

CAUTION: If oxygenating, make sure Oxygenation Delivery Tube is not pinched or below the Tubeframe and is easily accessed from the front.

10. Open the Pumphead Raceway and stretch the Pump Tubing Loop around the Infusion Pump. Close and latch the Pumphead Raceway.
11. Rotate the Pump Deck Locking Arm 90 degrees until it clicks into place.
12. Connect the Pressure Sensor Cable from the Pump Deck to the Pressure Sensor Connector on the Tubeframe.

13. If oxygenating, remove and set aside the Luer Lock Cap from the Oxygenation Delivery Tube and connect oxygen supply tubing (not included) from an oxygen source to the Oxygenation Delivery Tube.

CAUTION: Only use medical-grade oxygen that meets the regulatory requirements for compressed medical gas.

NOTE: Oxygen supply tubing is not provided by Organ Recovery Systems.

14. Press and hold the **POWER** button until you hear an audible beep, then release.
15. Press the **WASH** button to enter Wash Mode.
16. If oxygenating, turn on the oxygen and administer at a rate of 0.5 Liters/min for a minimum of 20 minutes.

CAUTION: During perfusate oxygenation, do not exceed an oxygen flow of 0.5 Liters/min to avoid overpressurizing the Organ Chamber while both Lids are secured.

CONSULT INSTRUCTIONS FOR USE: Follow the procedure outlined in the LifePort Kidney Transporter Disposable Cannula Instructions for Use (IFU) to cannulate and secure the kidney.

17. After oxygenation and once the kidney is ready to be placed into the Organ Chamber, turn off oxygen, disconnect the Oxygenation Delivery Tube from the Oxygenation Perfusion Circuit and fasten the Luer Lock Cap to the Oxygenation Perfusion Circuit to maintain aseptic conditions.

WARNING: The Luer Lock Cap must be applied to the Oxygenation Perfusion Circuit to prevent leakage or contamination of the aseptic field.

18. Remove the Outer Perfusion Circuit Lid.

CONSULT INSTRUCTIONS FOR USE: Refer to LifePort Kidney Transporter Disposable Sterile Drape IFU to maintain aseptic conditions.

19. *Using standard aseptic technique*, remove Inner Perfusion Circuit Lid.
20. *Using standard aseptic technique*, transfer the cannulated kidney in the Kidney Cradle to LifePort Kidney Transporter, being careful to avoid catching the Infuse Line.

CONSULT INSTRUCTIONS FOR USE: Refer to LifePort Kidney Transporter Operator's Manual to start the perfusion process and check for leaks.

21. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid.

CONSULT INSTRUCTIONS FOR USE: Follow the procedure outlined in the LifePort Kidney Transporter Disposable Sterile Drape IFU for removal from LifePort Kidney Transporter.

22. Replace and secure Outer Perfusion Circuit Lid.

CONSULT INSTRUCTIONS FOR USE: Follow the procedure in LifePort Kidney Transporter Operator's Manual to continue the perfusion process.

INTENDED USE
LifePort Kidney Transporter (LKT) is intended for use in continuous hypothermic machine perfusion of kidneys.

TARGET POPULATION
The target populations are patients eligible for kidney transplantation. The licensed kidney transplant surgeon is responsible for assessing patient eligibility to receive kidney transplantation. Patients have no contact with LifePort Kidney Transporter system.

INTENDED USERS
Primary users of LifePort Kidney Transporter system are medical professionals who are trained to operate LifePort Kidney Transporter system. It is expected that users of LifePort Kidney Transporter system have a substantive working knowledge and clinical experience with donor organ recovery, perfusion, and transplantation.

CLINICAL BENEFIT
Hypothermic machine perfusion of kidneys using LifePort Kidney Transporter system with KPS-1 Kidney Perfusion Solution has been demonstrated through clinical evidence to improve kidney function post transplantation by reducing delayed graft function.

DEVICE PERFORMANCE/PERFORMANCE CHARACTERISTICS
LifePort Kidney Transporter system is intended to be used with machine preservation solution to provide continuous hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient. The device maintains the organ in a cool, sterile organ container during perfusion and transport.

RESIDUAL RISK
Per the risk management report for LifePort Kidney Transporter, the overall residual risk is acceptable, and the appropriate methods are in place to obtain relevant product and postproduction information.

SERIOUS INCIDENT REPORTING
The user should report the occurrence of any serious incident to Organ Recovery Systems and to the competent authority of the Member State in which the user and/or patient is established.

CONTRAINDICATIONS
There are no known contraindications when used as directed.

DEVICE LIFETIME
LifePort Kidney Transporter Oxygenation Perfusion Circuit is a single use, disposable device. The sterile shelf life of an unopened device is 3 years, based on the available test data.

STORAGE CONDITIONS
Store between 2°C and 40°C. Avoid excessive heat and humidity. Keep dry and keep away from direct sunlight. Sterile unless package is damaged or open.

TECHNICAL ASSISTANCE
Please contact Organ Recovery Systems 24/7 Perfusion Helpline at +866.682.4800 (toll free in US), +32.2.715.0005 (Belgium), +1.352.721.5301 (Central and South America), or +33.967.23.00.16 (France).

WARNINGS AND PRECAUTIONS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

CAUTION: LifePort Kidney Transporter Disposable Products should be stored indoors in a dry location out of direct sunlight.

WARNING: Visually check LifePort Kidney Transporter Disposable Products. Do not use if parts are cracked, broken, or disconnected.

WARNING: For single use only. Do not reuse, reprocess or resterilize. Reusing, reprocessing, or resterilization of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or other serious patient complications.

WARNING: Use standard aseptic technique and universal precautions (e.g., gloves, masks, gowns, goggles or equivalent eye protection, biohazard bags) when handling the kidney, and when handling and disposing of LifePort Kidney Transporter Disposable Products and perfusate to prevent the possible transmission of pathogens to medical personnel and patients. The single practitioner, working alone must pay special attention to maintain these conditions.

WARNING: Before the operator begins to apply the LifePort Kidney Transporter Disposable Sterile Drape, the Outer Perfusion Circuit Lid should be removed. The exterior surfaces of the Outer Perfusion Circuit Lid are not considered part of a sterile field. Use standard aseptic technique when handling the interior surface.

WARNING: Oxygen must be handled in accordance with institutional safety procedures.

WARNING: Only experienced and properly instructed persons should handle oxygen.

WARNING: A fire may occur if oxygen comes in contact with a spark or other material that burns easily.

WARNING: Do not use electrical equipment that can produce a spark as it may ignite and burn when oxygen is in use.

WARNING: Do not smoke, light matches or use a lighter in a room where oxygen is being used.

WARNING: Do not use petroleum-based products.

WARNING: Use only oxygen approved lubricants and oxygen approved sealings.

WARNING: Room should be labeled with “Oxygen in Use” sign.

EXPLANATION OF SYMBOLS

	Warning/Caution		Use By, YYYY-MM-DD		Temperature Limits
LOT	Lot Number		Date of Manufacture, YYYY-MM-DD		Consult Instruction for Use
REF	Reference Number		Manufacturer		Keep Away From Sunlight
	Do Not Reuse		Do Not Resterilize		Keep Dry
STERILE EO	Sterile Medical Devices Using Ethylene Oxide		Do not use if package is damaged and consult instructions for use.	Rx Only	Prescription Medical Device
MD	Medical Device		Country of Origin		Importer
	Oxidizing Material		Single Sterile Barrier with protective packaging inside for aseptic field		

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